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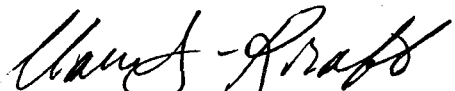
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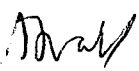
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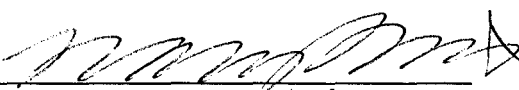
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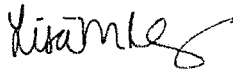
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Loss Trial

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## **ABSTRACT**

Obesity during youth has become a major public health problem. Overweight adolescents are at elevated risk for a variety of physical health problems and exhibit higher rates of eating pathology compared to non-overweight teens. Eating pathology has been suggested to contribute to overweight, and in some cases, complicate weight loss. A form of eating pathology common among overweight youth is binge eating. Many researchers have hypothesized that adults with binge eating may be less successful at weight loss, but this hypothesis has been met with mixed empirical support. Few adolescent studies have examined the impact of binge eating on weight loss. The present study seeks to evaluate the impact of binge eating on weight outcomes among adolescents during and after a placebo-controlled medication trial that included a behavioral weight loss program. Specifically, the present study aims to: (1) assess the impact of baseline binge and loss of control eating on weight loss and regain, (2) assess the impact of post-treatment binge and loss of control eating on weight regain, and (3) assess the impact of change in binge and loss of control eating on weight loss and regain. Findings from this study may help to guide treatment recommendations for obese adolescents.

IMPACT OF DISORDERED EATING AND PSYCHOLOGICAL FUNCTIONING ON  
OBESE ADOLESCENTS PARTICIPATING IN A PLACEBO-CONTROLLED MEDICATION  
AND BEHAVIORAL WEIGHT LOSS TRIAL

by

Lisa M. Ranzenhofer

Master's Thesis submitted to the faculty of the  
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## INTRODUCTION

### Background

#### *Overweight among youth*

Throughout the past three decades, the prevalence of obesity among children and adolescents has increased dramatically (Ogden et al., 2006). In 2003, the percentages of male and female adolescents categorized as overweight were 18.3% and 16.4%, respectively (Ogden et al., 2006). Current rates of adolescent overweight are of serious concern, as excess body weight is associated with negative health consequences that typically persist and often worsen throughout childhood into adulthood. Further, weight status tends to track throughout the life span, with present body weight playing an increasingly important role in future weight status as children grow older (Whitaker, Wright, Pepe, Seidel, & Dietz, 1997). Overweight children have an elevated risk of obesity during adolescence (Nader et al., 2006), and overweight adolescents have a higher risk for obesity during adulthood (Freedman et al., 2005; Whitaker et al., 1997). Among 12-14 year olds, 81% of overweight adolescents became overweight as adults. This association was strongest for African American girls, whose risk of obesity during adulthood was 90% for those who were overweight as teenagers (Freedman et al., 2005).

Overweight and obesity in adulthood are defined as a Body Mass Index (BMI;  $\text{kg/m}^2$ ) exceeding twenty-five and thirty, respectively. However, because adult standards for determining weight status are not applicable to growing children, definitions of obese and overweight for children and adolescents were established using percentile rankings for BMI. Growth charts were developed to reflect children's BMI percentile ranking according to their age and sex, which allow children to be classified according to weight status. Formerly, youth whose

BMI exceeded the 95<sup>th</sup> percentile were classified as overweight, and youth whose BMI was between the 85<sup>th</sup> and 94<sup>th</sup> percentile were considered at risk for overweight (Ogden et al., 2002). More recently, terminology has shifted to align more closely with adult terminology such that youth at or above the 95<sup>th</sup> percentile are classified as obese, and those between the 85<sup>th</sup> and 95<sup>th</sup> percentile are considered overweight (August et al., 2008). Throughout this manuscript, these terms—overweight and obese—will be used interchangeably to denote BMI greater than or equal to the 95<sup>th</sup> percentile, unless otherwise specified.

### ***Health consequences of overweight***

Overweight children are more likely than their non-overweight peers to suffer from a variety of health conditions. Sleep apnea, characterized by repeated respiratory disruptions during sleep, pseudotumor cerebri, which is elevated intracranial pressure in the absence of an actual tumor, and Blount's disease—disordered growth of the bones of the lower legs, and asthma, are all more common among overweight compared to non-overweight youth (Dietz, 1998). Sleep apnea can result in persistent fatigue due to compromised sleep quality, and pseudotumor cerebri and Blount's disease cause pain in the back and legs, respectively. Blount's disease can also cause difficulty with motility, perpetuating obesity. Further, health conditions that place youth at increased risk for cardiovascular and other diseases in the future, including hyper-lipidemia (elevated fasting blood lipid levels), hypertension (elevated blood pressure), and abnormal glucose tolerance (blunted insulin response), (Dietz, 1998), are more common among overweight youth than their healthy weight counterparts.

### ***Psychological correlates of overweight***

#### ***Psychosocial Functioning and Quality of Life***

The relationship between psychosocial functioning and obesity has shown some inconsistencies, but in general, more studies report a significant association. In a large, population based sample of 7<sup>th</sup>, 9<sup>th</sup>, and 11<sup>th</sup> grade adolescents, overweight girls and boys reported a variety of psychosocial problems more often than their non-overweight peers (Falkner et al., 2001). Overweight girls reported that they were less likely to spend time with friends and more likely to experience emotional problems and hopelessness compared to non-overweight girls. Further, overweight girls were more likely to consider themselves poor students and more likely to be held back a grade. In boys, overweight status was similarly related to problems with friends, considering oneself a poor student, and expecting to quit school (Falkner et al., 2001). By contrast, another study of adolescents in grades 7 through 12 found no significant differences between normal weight, moderately overweight, and severely overweight adolescents with regard to psychosocial concerns including emotional well-being, future job concerns, and social concerns (Neumark-Sztainer et al., 1997). In a third study, adolescents in grades 7-10 from a population based sample in London, England, were categorized as: underweight ( $< -1.0$  SD), normal weight ( $-1.0 - 0.9$ SD), overweight ( $1.0-1.9$  SD), and obese ( $>2.0$  SD). These investigators found that obese teenagers, compared to all other groups, had significantly higher prevalence of psychological distress. However, this relationship did not persist when boys and girls were analyzed separately (Viner et al., 2006).

Studies of quality of life (QOL) among overweight and normal weight adolescents are equally equivocal. In studies comparing health-related QOL in overweight compared to non-overweight adolescents, overweight was consistently related to having lower physical health-related QOL among treatment-seeking youth (de Beer et al., 2007; Fallon et al., 2005; Hughes, Farewell, Harris, & Reilly, 2007; Pinhas-Hamiel et al., 2006; Schwimmer, Burwinkle, & Varni,

2003; Stern et al., 2007; Williams, Wake, Hesketh, Maher, & Waters, 2005). Similarly, several studies suggest specific impairment in the social domain of QOL (de Beer et al., 2007; Fallon et al., 2005; Pinhas-Hamiel et al., 2006). Although no study has examined weight-based differences in QOL among a population-based sample of adolescents, findings from a childhood sample (mean age=10.4y) indicate that overweight status is related to impairment in physical and social QOL even in individuals not seeking treatment (Williams et al., 2005). Findings regarding other domains of QOL are mixed. Schwimmer and colleagues found overweight youth to be impaired across all domains of QOL, while several other childhood and adolescent studies found no weight-based differences with regard to emotional or school functioning (de Beer et al., 2007; Hughes et al., 2007; Pinhas-Hamiel et al., 2006). Pinhas-Hamiel and colleagues suggest that in the emotional and school domains of QOL, impairment is evident only among severely overweight and treatment-seeking youth, but not among individuals who are moderately overweight (Pinhas-Hamiel et al., 2006). An analysis of potentially different impacts of BMI on QOL among African American versus Caucasian adolescents indicated that social/interpersonal, self-esteem, and daily living QOL may be significantly more impaired among overweight adolescents who are Caucasian, compared to those who are African American (Fallon et al., 2005).

Parent-reports of their children's quality of life also appear to be influenced by the weight status of the child. Among overweight youth, parent-reported QOL was consistently lower than self-reported QOL, but among normal weight youth, parents' reported QOL was higher than the children's self-reports (Pinhas-Hamiel et al., 2006). Corroborating these findings, parents of overweight children (ages 5-12 years) reported significantly lower QOL than parents of non-overweight children across several domains of QOL (Hughes et al., 2007). The same study

found that the overweight children's self-report of QOL was only lower than normal weight youth in the domain of physical health. These findings suggest that a child's weight status may affect parents' perceptions of the child's QOL. Among adolescents, parents of overweight Caucasians reported significantly lower QOL for their adolescent children compared to parents of non-overweight Caucasians, but were no different from all African American children's parents' reported QOL (Fallon et al., 2005). This study corroborates the self-report findings that BMI has a greater impact on Caucasian's compared to African American's QOL.

### *Self-esteem*

Findings regarding the relationship between self-esteem and weight status are also inconsistent. French and colleagues reviewed 36 articles on the relationship between self-esteem and weight status and found that approximately half of cross-sectional studies reported that overweight children had lower self-esteem compared to non-overweight youth, and the remaining studies found no differences (French, Story, & Perry, 1995). In a second review, Wardle and Cooke (2005) analyzed 26 studies of weight and self-esteem and also concluded that the relationship is inconsistent (Wardle & Cooke, 2005). Discrepant findings may result from stratification based on demographic variables. Two studies found that overweight females, Caucasians, and Hispanics might be at increased risk for low self-esteem based on overweight status, compared to other groups of overweight children (Brown et al., 1998; Strauss, 2000). Several studies outside of the U.S. found self-esteem to be unrelated to body weight (Cortese et al., 2005; Erermis et al., 2004; Ozmen et al., 2007). One study that employed a domain-based perspective of self-esteem found that certain elements of self-esteem, such as physical appearance and athletic competence, were lower among overweight teens, but that other domains

were unrelated to weight status (Franklin, Denyer, Steinbeck, Caterson, & Hill, 2006). In this study, overall self-esteem was moderately lower among overweight teens.

### *Behavior Problems*

Assessment of behavior problems among overweight and healthy weight youth have generally studied younger children. Consistently, data have indicated that parents of overweight youth were more likely to report higher rates of internalizing (e.g., withdrawal) and externalizing (e.g., acting out) behavior problems among their children, compared to parents of non-overweight children (Banis et al., 1988; Braet, Mervielde, & Vandereycken, 1997; Stradmeijer, Bosch, Koops, & Seidell, 2000; Tanofsky-Kraff et al., 2004; Tershakovec, Weller, & Gallagher, 1994). Among adolescents who self-reported internalizing and externalizing behavioral symptoms, when BMI and body weight perception were studied concurrently, only body weight perception was related to behavior problems (ter Bogt et al., 2006).

### *Depression*

Despite a presumed link between obesity and depression among children and adolescents, empirical evidence is highly inconsistent. Although many researchers have investigated the hypothesis that overweight adolescents are more depressed than their healthy weight counterparts, most studies among non-treatment-seeking, community-based samples have not confirmed this hypothesis (Britz et al., 2000; Cortese et al., 2005; Falkner et al., 2001; Ozmen et al., 2007). By contrast, a study that included treatment-seeking and non-treatment-seeking overweight, and non-overweight, adolescents found that both overweight groups had elevated depression scores compared to the non-overweight group (Erermis et al., 2004). A study conducted among a national sample of 7<sup>th</sup> through 12<sup>th</sup> graders found that overweight adolescents



who were younger (12-14 years) did have elevated depressive symptoms, but this difference was not found among older teenagers (Swallen, Reither, Haas, & Meier, 2005).

Prospective studies of the relationship between weight status and depression reflect potential causality in both directions: Among women, being overweight during adolescence was associated with greater risk of major depressive disorder during adulthood (Anderson, Cohen, Naumova, Jacques, & Must, 2007; Erermis et al., 2004; Falkner et al., 2001; Neumark-Sztainer et al., 1997). Another study that evaluated the relationship between perceptions of being overweight at age 14 and depression at age 21, found that boys and girls who perceived themselves as overweight during adolescence had more mental health problems at age 21 than those who did not (Al Mamun et al., 2007). When actual BMI was included in the model, only perception of overweight, but not actual BMI, was related to subsequent depression. Conversely, Stice and colleagues found that depressive symptoms in adolescent girls are predictive of obesity onset over a four year follow up interval (Stice, Presnell, Shaw, & Rohde, 2005). This finding converges with childhood studies which suggest that depression during childhood, independent of weight or BMI, is associated with adulthood overweight (Goodman & Whitaker, 2002; Pine, Goldstein, Wolk, & Weissman, 2001).

### *Anxiety*

Similarly, there is limited empirical support for a relationship between anxiety and weight status during adolescence. In one study comparing rates of Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition, text Revised (DSM-IV-TR; (American Psychological Association, 2000) diagnoses between weight-loss treatment-seeking overweight, non-clinical overweight, and non-overweight youth, Britz and colleagues found no differences in prevalence of an anxiety disorder among overweight versus healthy weight adolescents from the population

(Britz et al., 2000). Further, in two childhood samples, anxiety symptoms were unrelated to weight status (Braet et al., 1997; Tanofsky-Kraff et al., 2004). Although no study has examined the cross-sectional relationship between symptoms of anxiety and weight status in adolescence, a prospective study beginning when participants were between 9 and 18 years of age found that those who were overweight as children were more likely to develop an anxiety disorder over the next twenty years (Anderson et al., 2007).

#### *Treatment-seeking versus non-treatment-seeking overweight youth*

Consistent findings document the elevated prevalence of general psychopathology among *clinical* samples of overweight youth. Numerous studies of treatment-seeking overweight adolescents found elevated depression, anxiety, behavior problems, and lower self-esteem among overweight youth seeking treatment, compared to non-treatment-seeking overweight and non-overweight teenagers (Britz et al., 2000; Erermis et al., 2004; Wardle & Cooke, 2005). The relationship between seeking treatment and psychopathology may be mediated via the construct of eating pathology. It is possible that individuals who suffer from eating pathology may be more likely to seek treatment compared to those who perceive themselves to eat normally. Indeed, there is strong evidence for a link between eating pathology and general psychopathology among overweight youth.

#### *Eating disordered behaviors and cognitions*

Eating disordered cognitions and behaviors comprise a myriad of maladaptive thoughts and behaviors related to eating, weight, and shape. Specific eating disordered behaviors include binge eating, as well as unhealthy and extreme strategies to control one's shape and weight.

#### *Binge eating*

Binge eating is defined as consuming an objectively large amount of food while feeling a sense of loss of control during eating (American Psychological Association, 2000). “Loss of control” over eating is the experience of not being in control of what or how much one is eating, or, “the feeling of not being able to stop eating,” regardless of the reported amount of food consumed. Currently classified as a research-category in the DSM-IV-TR, binge eating disorder (BED) is defined as engaging in at least 2 episodes of binge eating per week for a duration of at least six months, accompanied by marked distress regarding the eating episodes, as well as distress surrounding body shape and weight (American Psychological Association, 2000).

Among several large community samples of adolescents, rates of binge eating between 6% and 40% have been reported (Croll, Neumark-Sztainer, Story, & Ireland, 2002; French, Story, Remafedi, Resnick, & Blum, 1996; Johnson, Rohan, & Kirk, 2002; Neumark-Sztainer et al., 1997). The considerable discrepancy in reported rates of binge eating is likely the result of inconsistencies in how binge eating is defined and assessed across studies (Tanofsky-Kraff, 2008). Further, there is low concordance between interview and questionnaire methodology, and between parent and child reports of binge eating (Decaluwe & Braet, 2004; Field, Taylor, Celio, & Colditz, 2004; Johnson, Grieve, Adams, & Sandy, 1999; Steinberg et al., 2004; Tanofsky-Kraff et al., 2003; Tanofsky-Kraff, Yanovski, & Yanovski, 2005), suggesting that the construct of binge eating is subjectively interpreted.

Even among overweight youth, full-syndrome BED is relatively rare. However, binge and loss of control (LOC) eating episodes are more common among overweight youth (Decaluwe & Braet, 2003; Decaluwe, Braet, & Fairburn, 2003; Neumark-Sztainer, Falkner et al., 2002; Tanofsky-Kraff et al., 2004) and may constitute a marker for future development of full syndrome BED. Neumark-Sztainer et al. queried a community sample of 7<sup>th</sup> through 12<sup>th</sup> graders

and found that overweight adolescents engaged in binge eating more often than non-overweight teens (Neumark-Sztainer, Falkner et al., 2002). Further, among 126 children and adolescents (10-16y), those reporting binge episodes were heavier than those without such episodes (Decaluwe et al., 2003). Binge eating among treatment-seeking overweight youth appears to be even higher than among population-based samples (Decaluwe & Braet, 2003; Glasofer et al., 2007). Across samples of treatment-seeking overweight adolescents, estimates of the prevalence of binge eating range from about twenty to nearly sixty percent (Britz et al., 2000; Glasofer et al., 2007; Isnard et al., 2003).

#### *Other disordered eating behaviors*

“Weight control behaviors describe a constellation of practices designed to influence one’s shape or weight, which exist on a continuum ranging from healthy to unhealthy” pp. 258 (Goldschmidt, Aspen, Sinton, Tanofsky-Kraff, & Wilfley, 2008). Assessment of eating disordered behaviors among overweight youth can be difficult, as some weight control behaviors are normative and warranted among overweight youth, while others are related to the development of an eating disorder or another adverse mental or physical health outcome. Disordered eating behaviors consist of “extreme” weight control behaviors, including taking diet pills, self-induced vomiting, and using laxatives or diuretics, as well as “unhealthy” weight control behaviors, including fasting, eating very little, using food substitutes, skipping meals, and smoking cigarettes for weight control. Among large population samples of adolescents, data suggest that both extreme and unhealthy weight control behaviors are more common among overweight youth compared to non-overweight youth, with the heaviest teens reporting the most frequent use of such behaviors (Boutelle, Neumark-Sztainer, Story, & Resnick, 2002; Neumark-Sztainer, Story, Hannan, Perry, & Irving, 2002). Further, based on a population sample of both

girls and boys, it is thought that rates of both extreme and unhealthy eating behaviors tend to increase throughout adolescence (Neumark-Sztainer, Wall, Eisenberg, Story, & Hannan, 2006). “Healthy” weight control behaviors, including exercising, eating more fruits and vegetables, and eating fewer high fat foods and sweets, are also more prevalent among overweight youth, suggesting that overweight adolescents are more likely to engage in all types of weight-control behaviors.

### *Disordered Eating Cognitions*

Body dissatisfaction, shape concern, weight concern, body image, and overvaluation of shape and weight are constructs used to describe how one evaluates his/her shape or weight (Goldschmidt et al., 2008). Maladaptive, over-valuation of one’s shape is considered to be the core pathology of eating disorders (Goldschmidt et al., 2008). BMI is positively correlated with shape and weight concerns among adolescents (Lynch, Heil, Wagner, & Havens, 2008; Neumark-Sztainer, Story et al., 2002) and college students (Neighbors & Sobal, 2007). Similarly, among children, eating concerns, shape concerns, and weight concerns were more prevalent among overweight compared to normal weight youth (Burrows & Cooper, 2002; Dalton, Johnston, Foreyt, & Tyler, 2008; Tanofsky-Kraff et al., 2004).

### ***Relation between eating pathology and general psychopathology***

Despite equivocal relationships between overweight status and psychopathology, eating pathology has been consistently associated with psychological distress. Binge eating in adolescents is associated with a number of adverse psychosocial correlates. Adolescents who report binge eating are more likely to manifest a variety of problems including disordered eating cognitions, depressive symptoms, poorer family and social functioning, and emotional stress than those without binge eating (French et al., 1997; Johnson et al., 2002; Ledoux, Choquet, &

Manfredi, 1993) (Neumark-Sztainer & Hannan, 2000; Steiger, Puentes-Neuman, & Leung, 1991). These findings are consistent with adult studies (Grucza, Przybeck, & Cloninger, 2007; Telch & Agras, 1994). Further, among adolescents categorized as high-risk for eating disorders based on elevated weight and shape concerns and disordered eating behaviors, “high-risk” individuals were found to have elevated rates of depression, anxiety, stress, and binge eating compared to those with lower weight and shape concern (Doyle, le Grange, Goldschmidt, & Wilfley, 2007). Among community-based samples of adolescents, including both normal and overweight youth, eating disordered cognitions, including weight concern and thin body preoccupation, have been shown to predict the development of partial and full-syndrome eating disorders across several studies (Croll et al., 2002; Killen et al., 1996; The McKnight Investigators, 2003).

In summary, binge eating appears to be a highly relevant construct for adolescents despite that most youth do not meet full criteria for binge eating disorder. Binge eating is associated with a number of adverse psychosocial consequences as well as excess weight gain. The prospective link between binge eating and excess weight gain in youth suggests that binge eating may play an important role for adolescents seeking to lose weight.

### ***Weight loss treatment available to adolescents***

Despite a myriad of weight loss programs and strategies available to overweight adolescents, few have demonstrated notable efficacy. Strategies for weight reduction among overweight teenagers include traditional dietary and exercise based approaches, behavioral and cognitive approaches including behavior therapy and cognitive behavior therapy (CBT), pharmacologic interventions, and in extreme cases, bariatric surgery.

### ***Behavioral/psychological interventions***

Innumerable dietary, exercise, behavioral, cognitive, and psychological interventions, incorporating both outpatient and inpatient approaches, have been employed for weight loss. Behavioral interventions are believed to be most effective when a combination of strategies is employed. Across studies, the combined effectiveness of diet/exercise modifications with cognitive/behavioral interventions exceeds the effectiveness of either treatment modality alone (Johnson et al., 1997; Tsiros, Sinn, Coates, Howe, & Buckley, 2007). This is supported by the superiority of inpatient programs, which often incorporate a variety of strategies, compared to outpatient treatment (Braet, Tanghe, Decaluwe, Moens, & Rosseel, 2004; Rolland-Cachera et al., 2004). Some data suggest that child and adolescent (7-17 years) inpatients may lose up to half of their body weight during inpatient treatment (Braet et al., 2004). The majority of these programs demonstrate success during and immediately after treatment, but participants often regain weight after treatment has ended (Braet et al., 2004; Epstein, Myers, Raynor, & Saelens, 1998; Rolland-Cachera et al., 2004; Tsiros et al., 2007; Wadden, 1993). Most studies, even those incorporating intensive treatment modalities, are marked by high rates of weight regain. In one study of severely obese adolescents who participated in an inpatient program that included a 1,750 kcal diet, study completers regained an average of two-thirds of weight lost at the one-year follow-up. This finding excluded patients who refused to follow the diet during the intervention, and those who were lost to follow-up (Rolland-Cachera et al., 2004), constituting a conservative estimate of actual rates of weight regain. In a second study of children and adolescents, individuals regained an average of nearly half of weight lost during treatment (Braet et al., 2004). Further, in a ten-year follow-up study of arguably one of the most effective behavioral childhood intervention to date, participants were less overweight at the 5 year follow up compared to 10 year follow-up (Epstein, Valoski, Wing, & McCurley, 1990), suggesting that without continued

intervention, the majority of individuals who lose weight may have tendency to regain lost weight.

### *Very Low Calorie Diets*

Very low calorie diets have similarly demonstrated short-term efficacy among youth (Figueroa-Colon, Franklin, Lee, von Almen, & Suskind, 1996; Sothorn, Udall, Suskind, Vargas, & Blecker, 2000) and adults (Ryttig, Flaten, & Rossner, 1997; Yanovski, Gormally, Leser, Gwirtsman, & Yanovski, 1994). Very low calorie diets are characterized by marked restriction of caloric intake (intake in the range of ~420-800 kcal/day; (Ryttig et al., 1997; Sothorn et al., 2000)), and therefore induce greater and faster weight loss compared to other hypocaloric diets. However, similar to other approaches, very low calorie diets tend to be associated with weight regain. Few long term studies of very low calorie diets in adolescents have been conducted, although adult studies support that long term results of very low calorie diets were inferior to behavioral and combined interventions (Miura, Arai, Tsukahara, Ohno, & Ikeda, 1989). In this study, 67% of adults randomized to very low calorie diets alone regained weight, while 75% and 85% of patients in the combined therapy and behavior modification groups maintained their weight loss at two year follow up (Miura et al., 1989).

### *Medication*

When dietary and behavioral weight loss interventions fail, more intensive treatment options including pharmacotherapy and bariatric surgery may be warranted. A review of pharmacologic treatments for overweight adolescents include studies of Orlistat and Sibutramine, both of which demonstrated efficacy compared to placebo (Dunican, Desilets, & Montalbano, 2007). Despite methodological limitations in both studies, the strongest mean effects were a loss of 4.09 BMI units for orlistat (Ozkan, Bereket, Turan, & Keskin, 2004), and



5.6 BMI units for sibutramine (Violante-Ortiz et al., 2005). Side effects for both medications are notable. Orlistat often causes gastrointestinal problems (flatulence, loose stools), and sibutramine has been shown to cause increases in blood pressure and heart rate (Dunican et al., 2007; R. S. Padwal & Majumdar, 2007). Among adults, a review of both orlistat and sibutramine for weight control similarly concluded that both medications are moderately effective for weight loss, but many studies were characterized by significant attrition and so results must be interpreted accordingly (R. Padwal, Li, & Lau, 2004). Few adolescent studies have included long-term follow-up of medication-based interventions, but in one study of sibutramine with a 2 year follow-up interval, a significantly greater percentage of patients randomized to a sibutramine regimen maintained weight loss at 2 year follow-up compared to placebo treatment, suggesting long-term efficacy of sibutramine (James et al., 2000). A review of adult literature suggests that weight regain ensues upon discontinuation of pharmacotherapy, and these authors question pharmacotherapy as an adequate anti-obesity therapy (R. S. Padwal & Majumdar, 2007).

### *Bariatric Surgery*

Bariatric surgery for weight reduction is recommended only in extreme cases wherein obesity is severe, is associated with related health co-morbidities, and when the individual has failed at structured weight loss programs. Bariatric surgery has demonstrated greater efficacy compared to other weight loss modalities, even in cases of mild to moderate obesity (O'Brien et al., 2006). In an analysis of several studies wherein gastric bypass surgery was employed among adolescents, mean weight reduction was 60% of body weight, yet adolescents remained 40% above their ideal body weight (Tsiros et al., 2007). In a sample of thirty-three severely obese adolescents who were followed for over a decade after surgery, weight loss was significant at 1,

5, 10, and 14 years post-treatment (Sugerman et al., 2003). In this single adolescent study examining patients up to 14 years after surgery, the nadir of weight loss occurred at approximately five-years post-surgery, after which weight and BMI appeared to rise slowly, but remained significantly lower than pre-operative weight (Sugerman et al., 2003). Notably, this analysis excluded five patients who had regained all or most of their lost weight at 5 and 10 years. Excluding these patients, adolescents' weight at five-year follow-up fell into a non-obese category (mean BMI =  $29 \pm 5$  kg/m<sup>2</sup>). The authors do not indicate whether an intent-to-treat analysis was employed, and results should be interpreted in light of these limitations.

Practitioners emphasize the necessity that adolescents and families of adolescents undergoing bariatric surgery be well informed, motivated, and undergo extensive psychological assessment prior to surgery (Dziurawicz-Kozłowska, Wierzbicki, Lisik, Wasiak, & Kosieradzki, 2006; Inge et al., 2004; Strauss, Bradley, & Brolin, 2001). To maximize treatment benefit, psychological assessment should address family functioning, coping skills, and severity of psychosocial co-morbidities, to determine candidacy for surgery as well as identify issues to be addressed prior to and after surgery (Inge et al., 2004).

#### *Weight Maintenance Interventions*

No studies have examined potential weight maintenance interventions among adolescents, but there is some support for the efficacy of maintenance interventions among children and adults. Among children, one study compared behavior skills maintenance and social facilitation maintenance interventions to a control condition and found that both interventions were superior to the control group, but were not significantly different from each other, in preventing weight regain (Wilfley et al., 2007). However, the protective effect of the maintenance intervention waned over time and the authors conclude that better maintenance

strategies are needed (Wilfley et al., 2007). There was also an interaction between baseline social problems and long-term effect of treatment. Children who had low levels of social problems at baseline in both groups experienced significantly better weight maintenance compared to the control group, while there was no treatment group effect for children with high levels of social problems at baseline.

Among adults, Jeffery and colleagues (2000) reviewed several approaches to long-term weight maintenance. These approaches included increasing intensity of initial treatment, increasing treatment duration, altering diet and exercise recommendations, enhancing motivation, and teaching maintenance-specific skills. However, the authors concluded that none of these has shown substantial efficacy to date (Jeffery et al., 2000). In a randomized controlled trial, Wing and colleagues conducted in-person and internet-based weight maintenance interventions based on self-regulation theory, in which participants were instructed to monitor their weight and adjust their behavior accordingly (Wing, Tate, Gorin, Raynor, & Fava, 2006). Results of this study indicate significant superiority of the face-to-face intervention compared to both the internet intervention and a control group: participants in the face-to-face group regained  $2.5 \pm 6.7$  kg compared to  $4.7 \pm 8.6$  kg in the internet group and  $4.9 \pm 6.5$  in the control group. Further, attendance was better, and a higher proportion of individuals maintained their weight, in the face-to-face intervention (Wing et al., 2006).

#### *Secondary outcomes*

A number of studies have investigated the effects of weight loss treatment on psychological constructs such as eating disordered cognitions and self-esteem, but few have examined adolescents only. Among an inpatient sample of children and teenagers ages 7-17 years, Braet and colleagues found improvements in self-esteem and several aspects of eating

pathology, including drive for thinness, body dissatisfaction, and weight, shape and eating concerns, from baseline to post-treatment (Braet et al., 2004). Moreover, the number of binge eating episodes per month, as well as the number of participants endorsing binge eating, decreased from baseline to post-treatment. All improvements in eating related and general pathology were maintained at 14-month follow up (Braet et al., 2004).

Self-esteem has also been shown to improve in response to weight loss interventions. In a review of published findings on self-esteem changes during weight management programs, Lowry et al. document eight studies of adolescents only, the majority of which generally demonstrated significant improvements in self-esteem from baseline to post treatment. Two of these studies included further follow-up on the maintenance of self-esteem change, one of which found that the change persisted after the conclusion of the program, and the other did not (Lowry, Sallinen, & Janicke, 2007). These two studies did not address whether persistence of self-esteem improvement was related to weight maintenance.

### ***Impact of binge eating on treatment outcome***

Several studies suggest that binge eating and BED may hinder weight loss treatment outcomes, however, this hypothesis has received mixed empirical support. In an early study, Marcus and colleagues (1988) found that obese women with and without binge eating lost comparable amounts of weight during a behavioral weight loss program, but that women with binge eating at baseline regained more weight at six month follow up (Marcus, Wing, & Hopkins, 1988). However, this difference did not persist at the 18-month follow-up. In another study wherein patients engaged in a comprehensive very low calorie diet treatment regimen, obese women with and without BED did not differ significantly in terms of overall weight loss (Yanovski et al., 1994). In this study, a greater proportion (35%) of women with BED had a

poor treatment outcome, as defined by regaining > 50% of initial weight or dropping out of treatment, compared to 0% of participants without BED. Among a larger sample of women, baseline binge eating status was similarly non-predictive of weight loss immediately after treatment, but was weakly related to less weight loss one year after the conclusion of treatment. (Sherwood, Jeffery, & Wing, 1999). Binge eating may also influence likelihood of attrition, with binge eaters being more likely to drop out of treatment across a variety of therapeutic modalities (Marcus et al., 1988; Sherwood et al., 1999; Teixeira et al., 2004).

Blaine and Rodman (2007) conducted a meta-analysis of studies that examined the impact of binge eating and BED on weight loss treatment outcome, which included 36 matched analyses and a cumulative sample of 792 men and women with and without BED. This meta-analysis suggested that individuals with BED fare worse during treatment, with non-binge eaters losing about four times more weight compared to individuals with BED, controlling for attrition rates (Blaine & Rodman, 2007). This study also examined potential treatment moderators and found that pre-treatment weight status moderated the relationship between binge status and weight loss, with heavier individuals potentially driving the effect.

Studies of the effectiveness of bariatric surgery among individuals with and without BED are contradictory. Kalarchian and colleagues (1999) found that pre-operative binge eaters and non-binge eaters were not significantly different in terms of eating behaviors (hunger and disinhibition) or change in BMI, at four months after surgery (Kalarchian, Wilson, Brolin, & Bradley, 1999). Dymek et al. (2001) similarly found no differences in eating behavior after surgery, however, individuals who reported pre-operative binge eating lost less weight compared to those without binge eating (Dymek, le Grange, Neven, & Alverdy, 2001). Finally, a third study found that individuals who reported pre-operative binge eating demonstrated persistence of

elevated hunger and disinhibition after surgery, as well as poorer weight outcomes, compared to individuals without pre-operative binge eating (Green, Dymek-Valentine, Pytluk, Le Grange, & Alverdy, 2004). Discrepant results across studies may result from inadequate follow-up study of participants.

In studies with longer follow-up, findings reflect greater consensus regarding outcomes of adults with and without binge eating. Among several prospective adult studies including follow-up periods greater than 18 months, individuals with BED regained more weight after surgery compared to those without BED (Guisado et al., 2003; Kalarchian et al., 2002; Pekkarinen, Koskela, Huikuri, & Mustajoki, 1994; Sallet et al., 2007). By contrast, one surgical study that included a component of psychological therapy for all BED patients found no differences in percent excess weight loss between those with and without BED, suggesting that management of BED via psychological treatment can enable binge eaters to have positive outcomes after gastric banding (Busetto et al., 2005).

A recent study of over 5,000 adults with Type II diabetes mellitus was the first large scale trial to examine the influence of binge eating at both baseline and post-treatment on treatment outcome (Gorin et al., 2008). Participants were categorized into four groups based on presence of binge eating at baseline and 1 year. Yes/yes: reported binge eating at both times, yes/no: reported binge eating at baseline but not at 1 year, no/yes: reported binge eating at 1 year but not at baseline, and no/no: participant did not report binge eating at either time. Findings from this trial indicated significant differences in weight loss based on binge eating over time. Participants in the yes/no and the no/no group had significantly greater weight loss compared to the yes/yes, and the no/yes groups. The authors conclude that binge eating is likely to remit during treatment

and that as long as binge eating ceases, baseline binge eating is not detrimental to treatment outcome.

To our knowledge, the impact of binge eating on treatment outcome has not been investigated in a sample of exclusively adolescents. An inpatient study of 7-17 years olds participating in an intensive, 10-month inpatient weight loss program (Braet et al., 2004) found no between-group differences in overall weight loss when comparing children who reported at least one binge eating episode versus children who reported no episodes. This study also reported that degree of binge eating was reduced from 56% to 19% by post-treatment. The absence of a difference in weight loss between those with and without binge eating at baseline may be because the influence of post-treatment binge eating on weight outcome was not evaluated in this study. It is possible that children who ceased to binge eat encountered the most treatment success, and those who failed to stop binge eating encountered treatment failure, resulting in similar mean weight loss when compared to children who never experienced binge eating.

In a number of prospective studies, eating disordered behaviors have been shown to predict weight gain over time. Among adolescent girls, several prospective studies cite eating disturbances, including dietary restraint (Stice et al., 2005), self-reported dieting (Field et al., 2003; Stice, Cameron, Killen, Hayward, & Taylor, 1999), extreme weight control behaviors (Stice et al., 2005) and binge eating (Stice et al., 1999) as risk factors for excess weight gain. Neumark-Sztainer and colleagues studied adolescent boys and girls with a mean age of 14.5 years, and similarly found that personal weight concerns, as well as dieting and unhealthy weight-control behaviors, predicted attaining overweight status over a five year interval (Neumark-Sztainer et al., 2007). Among children (ages 6-12 years) at high-risk for adult obesity

based on having an obese parent and/or current obesity, both binge eating and dieting, but not disturbed eating attitudes, predicted increased fat gain over a four year time period (Tanofsky-Kraff et al., 2006). Conversely, across several studies of adolescents, actual BMI, as well as BMI gain over time, was shown to be positively associated with increases in body dissatisfaction and weight concerns over the study interval (Field et al., 2001; Presnell, Bearman, & Stice, 2004). Prospective analyses suggest that weight control behaviors and eating pathology may play a causal role in excess weight gain, but it is also possible that such behaviors and attitudes are merely a marker for propensity to gain excess weight.

Recent literature has focused on the relative contributions of the reported amount of food consumed versus the experience of LOC over eating, to pathological outcomes. Some researchers (Tanofsky-Kraff, 2008) have posited that the experience of LOC, rather than the reported amount of food consumed per se, is problematic for several reasons: First, assessment of what constitutes a large amount of food, in growing boys and girls, is often ambiguous. Second, it is possible that the experience of not being able to stop eating, is emotionally pathological, even if the amount of food consumed is not large. It is possible that either construct: binge eating, and/or simply LOC eating, may be related to treatment outcome. Supporting the salience of the experience of LOC to eating pathology, LOC eating has demonstrated a number of adverse correlates. Among a treatment seeking sample of children between ages 6 and 10, those who endorsed LOC eating within the 6 months prior to assessment had higher BMI, higher body fat mass, greater symptoms of depression and anxiety, and more body dissatisfaction, compared to children without LOC (Morgan et al., 2002).

### *Theoretical models of obesity*



The etiology of obesity, like most diseases, is multi-faceted, and a number of theoretical models are useful in explaining obesity. The energy balance model depicts the currently accepted physiological mechanism underlying weight change. The energy balance model posits that excess of intake over expenditure produces weight gain, excess of expenditure over intake produces weight loss, and equivalent intake and expenditure produce weight stability (Deriaz, Tremblay, & Bouchard, 1993). Although many people successfully lose weight, few are able to maintain weight loss. A number of proposed theoretical models suggest mechanisms by which psychosocial or emotional factors may affect (or hinder) weight outcomes.

Two models incorporating upstream psychosocial and emotional factors into a proposed etiological model of obesity that have received support in the literature are affect regulation theory and restraint theory. Affect theory (Figure 1) posits that human emotions represent nine distinct affects that produce and explain approach/avoidance behavior in humans. Stimuli that produce positive affect will be sought, while those that produce negative affect will be avoided. Accordingly, food may be sought to alleviate states of negative affect. Indeed, negative affect is the most commonly cited reason for binge eating (Polivy & Herman, 1993; Stickney, Miltenberger, & Wolff, 1999). Binge eating behavior seems to be negatively reinforced by the temporary alleviation of negative affect during the course of a binge episode (Deaver, Miltenberger, Smyth, Meidinger, & Crosby, 2003), despite that negative affect reappears after the conclusion of the eating episode.

A number of mechanisms may account for the temporary reduction of negative affect via binge eating. Psychologically, binge eating has been suggested to temporarily reduce negative affect by serving as a coping strategy (Arnold, Kenardy, & Agras, 1992), or as an “escape” from self-awareness (Heatherton & Baumeister, 1991). Arnold and colleagues suggest that binge

eaters may use eating to cope with negative emotions, presumably when an individual lacks adaptive coping strategies in his/her repertoire. Similarly, Heatherton and Baumeister suggest that the act of eating enables people to shift from higher to lower levels of self-awareness, allowing an “escape” from painful or threatening stimuli that otherwise enter awareness. Thus, binge eating reduces one’s experience to physical stimuli and sensations, allowing an escape from threats and worries (Heatherton & Baumeister, 1991). Via these mechanisms, negative emotions may serve as perpetuating factors for overeating and obesity. Physiologically, food consumption influences the 5-HT (serotonin) system, implicated in mood (Smith, Fairburn, & Cowen, 1999; Steiger et al., 2005), such that binge episodes may temporarily enhance mood via a physiological pathway.

Another commonly cited theoretical model of obesity is restraint theory (Polivy & Herman, 1985). In contrast to affect theory, which posits that negative affect precedes binge eating, restraint theory posits that perceived or actual dietary restriction is the initiating factor in a cycle of binge eating. Restraint theory suggests that restriction ultimately results in disinhibition and subsequent binge eating, especially under vulnerable conditions such as stress or anxiety.

The theoretical grounding for the present study is rooted in the energy balance model, as well as both affect and restraint theory. The positive correlation between binge eating and intake suggests why binge eating may hinder treatment outcome. Affect theory and restraint theory propose upstream factors that may promote binge eating. A key aspect of the conceptual basis for the present study is that behavioral weight loss may suppress binge eating without addressing upstream emotional or psychological factors driving the behavior. Therefore, binge eating may be temporarily suppressed during treatment but would be likely to remit following termination of

treatment. It is possible that factors that promote weight loss differ from those that promote weight maintenance.

### **Study Rational and Purpose**

Overweight among youth is a substantial problem, and to date, weight loss treatment success is minimal. A number of adult studies suggest that binge eating plays a contributory role in overweight and may hinder weight loss. Yet, the long-term impact of binge eating on weight trajectories during and after weight loss is unclear among adults, and not well studied among children and adolescents. Further, most existing studies have examined baseline binge eating only, and have not studied whether the persistence of binge eating at post-treatment impacts long-term weight maintenance or regain. The current study aims to test the hypotheses that baseline and post-treatment binge eating affect weight loss as well as weight maintenance. At present, no study has examined the impact of baseline and post-treatment binge eating on weight loss and weight regain in a sample of severely overweight adolescents.

### **Specific Aims, Hypotheses, and Data Analytic Strategy**

This study has three specific aims. The first aim will be to determine the impact of baseline binge and LOC eating on weight outcomes during and after weight loss treatment. The second specific aim will be to investigate the impact of post-treatment binge and LOC eating on weight regain during the follow up period. Finally, we will investigate how a change in presence or frequency of binge or LOC eating affects both weight loss and weight regain.

*Aim One: Impact of baseline binge and LOC eating on weight outcomes.*

#### *A. Impact of baseline binge/LOC eating on weight loss*

Based on previous research, it is hypothesized that adolescents who endorse binge/LOC eating at baseline will lose less weight compared to individuals who do not endorse LOC

eating. This hypothesis is based on an adult meta-analysis in which adults with BED lost nearly four times less weight compared to those without the disorder (Blaine & Rodman, 2007). In the present study, binge/LOC eating will be operationalized as a dichotomous variable according to endorsement of  $\geq 1$  binge episode on the Eating Disorder Examination (EDE) at baseline.

*B. Impact of baseline binge/LOC eating on weight regain*

It is hypothesized that adolescents who endorse binge/LOC eating at baseline will regain more weight after the conclusion of treatment, compared to adolescents who do not endorse binge/LOC eating at baseline. This hypothesis is based on the work of Blaine and Rodman, and additional studies in which adults who endorsed binge eating regained more weight compared to adults without binge eating, across a variety of treatment modalities (Dymek et al., 2001; Green et al., 2004; Kalarchian et al., 2002; Marcus et al., 1988; Sherwood et al., 1999).

*Data analytic strategy for Aim One*

Linear mixed models will be used to examine the influence of baseline binge/LOC eating on participants' weight loss during the treatment phase of the study, and weight regain during the follow-up phase of study. BMI at all time points ranging from the start of the study through six months will constitute the dependent variable for weight loss. BMI at all time points from month six through twelve will constitute the dependent variable for weight regain.

*Aim Two. Impact of post-treatment binge/LOC eating on weight outcomes*

*A. Impact of post-treatment binge/LOC eating on weight re-gain*

Similar to our hypothesized effect of baseline binge and LOC eating on weight outcome, it is hypothesized that post-treatment binge or LOC eating will be associated with greater

weight regain after the end of treatment. Again, endorsement of  $\geq 1$  binge episode or LOC episode according to the EDE will be used to operationalize LOC eating.

*Data analytic strategy for Aim Two*

Similar to Aim 1, Linear mixed models will be used to examine the influence of baseline binge/LOC eating on participants' weight loss during the treatment phase of the study, and weight regain during the follow-up phase of study. BMI at all time points from month six through twelve will constitute the dependent variable for weight regain.

*Aim Three. Impact of change in binge and LOC on weight outcomes*

*A. Impact of change in binge/LOC eating on weight loss*

It is hypothesized that adolescents who either stop binge/LOC eating entirely or decrease the frequency of binge eating during treatment will lose more weight during treatment compared to other adolescents. The work of Gorin and colleagues (Gorin et al., 2008) supports this hypothesis. Change in binge eating will be operationalized as the number of binge/LOC eating episodes endorsed within the month prior to assessment at post-treatment, minus the number of binge eating episodes endorsed within the month prior to assessment at baseline. Primary analyses will examine change in binge eating as a categorical variable. Participants will be classified as: 1). Never endorse binge/LOC eating, 2). Stop or decrease frequency of binge/LOC eating, or 3). Start or increase frequency of binge/LOC eating. We will also examine change in binge/LOC frequency as a continuous variable, however, because of its abnormal distribution, this will not constitute the primary dependent variable.

*B. Impact of change in binge/LOC on weight regain*

There is a paucity of data on which to base a hypothesis regarding the impact of a change in binge/LOC eating on weight regain among individuals who did and did not endorse binge eating at baseline. No study has examined post-treatment binge eating as a predictor of subsequent weight regain. We therefore extrapolate findings from Gorin et al., (Gorin et al., 2008), to predict that reportedly stopping binge eating will be reliable, and that those who report stopping or never binge eating will regain less weight than those who start or continue binge eating.

#### *Data Analytic strategy for Aim Three*

Similar to Aim 1, linear mixed models will be used to examine the impact of change in binge and LOC status and frequency on weight loss and regain. A categorical variable comprising the three binge/LOC groups will constitute the primary independent variable. Number of episodes at post-treatment minus the number of episodes at baseline will constitute change in binge/LOC eating as a continuous variable. BMI at all time points from the first day of treatment to six months will constitute the dependent variable for weight loss, and BMI at all time points from six months through one year will constitute the dependent variable for weight regain.

#### **Power Analysis**

The data set from the parent study consists of 168 participants. Sample-size calculations for mixed measures procedure can be calculated based on differences between means (change scores) as well as differences between slopes. Using estimated weight loss and standard deviations from a previous adult analysis as a guide, we used both methods (difference in means, difference in slopes) to project a requisite sample size for the present research question. Adult data was not completely transferable to the present equation because most studies examining the

impact of binge eating on weight loss reported weight loss in kilograms, as opposed to BMI. In our calculation, we projected a smallest meaningful difference in weight loss of .5 BMI units between groups, with a common standard deviation of .7 – 1.0 BMI units. Accounting for a 3:1 ratio of youth without and with LOC respectively, it was determined that about 88 participants were needed for the present analysis: 22 with, and 66 without, LOC. nQuery ® (Elashoff, 1999-2005) statistical software was used to estimate sample size based on parameters from previous studies and estimated parameters. Our second sample size calculation involved examining potential differences over time (changes in slope). We approximated the number of visits per child as 15 and the smallest meaningful change in BMI from one visit to the next as .02 BMI units. In this analysis, it was determined that 23-25 participants per group were needed to detect such a difference. Calculations for analysis of sample size for continuous longitudinal data were based on equations from Analysis of Longitudinal Data (Diggle, Liang, & Zeger, 1994). For both calculations, assumed alpha was set at 0.05 and power was set at of 80%. It appeared from perspectives that our sample size of 168 would suffice for testing of the present hypotheses.

### **General Data Analytic Strategy**

SPSS (v.16) is a statistical software package commonly employed to analyze data from the social sciences and will be used in the present study for all data analyses. Mixed models will be employed to examine the impact of various predictor variables on adolescents' BMI over time. Mixed models can accommodate longitudinal data with unbalanced follow-up intervals, which is appropriate for the present data set since follow-up intervals were highly variable. BMI, as opposed to BMI Z-score, constituted the dependent variable as recommended by Berkey et al., and Cole et al. (Berkey & Colditz, 2007; Cole, Faith, Pietrobelli, & Heo, 2005). The rational for using BMI as opposed to BMI Z-score is that within-subject variability in BMI Z-

score is correlated with baseline BMI-Z, but not BMI. In the current study wherein adolescents with a wide-range of BMI and BMI-Z scores were examined, use of BMI-Z scores would weight the BMI change for heavier youth more strongly than equal BMI change for lighter youth.

The primary independent variables are binge and LOC eating and medication assignment. Covariates considered in each model included sex, race, pubertal status, depressive symptoms, and baseline BMI. Adolescent-specific random intercepts account for variability in baseline BMI not explainable by the independent variables of interest. We will examine several error structures including compound symmetry and serial correlation and choose the structure with the best fit to the data. Model parameters were estimated by restricted maximum likelihood using SPSS 16. Confidence intervals were computed using t-statistics.

## **METHOD**

### **Design**

The present study sought to examine an archived database of participants in a double-blind, randomized, placebo-controlled medication trial with a behavioral weight loss component. A de-identified database from the Unit on Growth and Obesity at the Eunice Kennedy Shriver National Institute of Child Health and Human Development, comprising a sample of overweight, male and female, Caucasian and African American adolescents (12-17y) seeking weight-loss treatment, was obtained. The database included anthropometric measures such as weight and height, as well as interviews and questionnaires regarding eating behaviors and attitudes, and other psychosocial characteristics. Existing data was obtained and analyzed to examine the relationships between anthropometric data (i.e. patient BMI at baseline and post-treatment) and eating behaviors as



measured by a semi-structured clinical interview. Overweight (BMI  $\geq 95^{\text{th}}$  percentile, Ogden, 2002 #58}) male and female overweight African American and Caucasian adolescents, who have an obesity-related co-morbid health condition, were included in the parent study.

### **The Parent Study**

The parent trial sought to examine the safety and efficacy of orlistat for weight loss among adolescents aged 12-17 years. For the first six months of the study, all participants concurrently underwent two treatment modalities: a 12-week behavior modification program, as well as 24 weeks of randomized orlistat or placebo. The first six months of the study constituted the randomized phase of treatment. Upon completion of post-treatment testing, all participants were offered the opportunity to take open-label orlistat medication for the subsequent six months (months 6-12), which constituted the open-label phase of treatment. BMI was assessed at baseline, at weeks 1-12, 16 (month 4), 20 (month 5), post-treatment (month 6), and months 8, 10, and 12 (1 year). Binge/LOC eating and all psychological variables were measured at baseline and post-treatment (6 months). Figure 3 displays the study timeline.

### **Participants**

Adolescents were recruited for the parent trial through newspaper advertisements and mailings to families and physicians for a clinical weight loss trial involving medication (Anon, 2005a, 2005b). Caucasian and African American adolescents who had a BMI greater than or equal to the 95<sup>th</sup> percentile along with at least one obesity-related co-morbid condition were eligible for the study. Qualifying co-morbidities included insulin resistance (fasting insulin  $\geq 15$  mg/dl), hyperlipidemia (cholesterol  $\geq 200$  mg/dl or LDL cholesterol  $\geq 129$  mg/dl), hypertension (3 blood pressure readings  $\geq 130/90$ ), sleep apnea, pseudotumor cerebri, joint pain, or another

obesity-related medical complication. Exclusion criteria included pregnancy or a non obesity-related physical or psychiatric health condition.

The parent study was approved by the National Institutes of Child Health and Human Development Institutional Review Board, and the present study was approved by the Uniformed Services University of Health Sciences Institutional Review Board. All data that was used for the present investigation was provided with written consent and assent by parent and child, respectively, during the consent procedure for the parent study.

### **Measures**

All measures were completed at baseline and post-treatment. Weight was measured at baseline, at weeks 1-12, 16 (month 4), 20 (month 5), post-treatment (month 6), months 8, 10 and 12, and height was measured at baseline, 6 months, and 1 year. All baseline measures were completed prior to the initiation of any treatment.

### ***Interviews and questionnaires***

#### ***Eating Disorder Examination***

The Eating Disorder Examination (EDE; (Fairburn & Cooper, 1993) and Child Eating Disorder Examination (ChEDE; (Bryant-Waugh, Cooper, Taylor, & Lask, 1996) are structured clinical interviews administered to adults, adolescents, and children to assess binge and LOC eating behaviors. The ChEDE differs from the adult version only in that its wording is adjusted to make the measure more accessible to children. Interviewers who underwent extensive clinical training administered the EDE and ChEDE (Glasofer et al., 2007). The semi-structured nature of the EDE and ChEDE allow for explaining concepts and giving examples, to ensure that participants fully understand the questions. The EDE and ChEDE are validated for children ages 12 and over, and 8 and over, respectively. The EDE is considered the gold standard measure for

assessing eating disorders and has demonstrated sound psychometric properties, across studies. Investigations of the adult EDE demonstrate good discriminant and concurrent validity, internal consistency, interrater reliability, and test-retest reliability (Fairburn & Cooper, 1993; Glasofer et al., 2007; Rizvi, Peterson, Crow, & Agras, 2000; Tanofsky-Kraff et al., 2004; Williamson, Anderson, Jackman, & Jackson, 1995). .

Eating episodes were classified as objective binge episodes (OBEs), subjective binge episodes (or LOC eating), objective overeating (OO) without LOC, or no episode. OBEs are episodes involving reports of unambiguously large amounts of food, as well as the experience of LOC. LOC eating episodes similarly involve the experience of loss of control, but the reported amount of food eaten was not considered unambiguously large. When two or more types of eating episodes were reported, participants' were classified according to the most pathological episode they have experienced, with binge episodes trumping LOC eating, LOC trumping OO, and OO trumping no episodes. For the purposes of the present study, binge episodes involve only episodes when large amounts of food are reportedly consumed and LOC eating includes episodes wherein both reportedly large and smaller amounts of food are consumed.

#### *Children's Depression Inventory*

The Children's Depression Inventory (CDI): To assess general depressive symptoms, children completed the CDI (Kovacs, 1992), a validated 27-item measure that assesses depressive symptoms in children. The CDI was adapted from the Beck Depression Inventory (BDI; (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), with phrasing adjusted to make the measure more accessible to children. CDI items consist of three responses that are graded in severity ranging from 0-2, with 2 being the most pathological. For example, regarding suicidality, possible CDI responses include: "I do not think about killing myself," "I think about

killing myself but I would not do it,” and “I want to kill myself.” Individual CDI items comprise five subscales: negative mood, interpersonal problems, ineffectiveness, anhedonia, negative self-esteem, as well as a total score. Then a total score is computed by summing individual subscale scores; total score may range from 0-54. A total score of 19 is considered the minimum cutoff for clinical depression; this value represents the 90<sup>th</sup> percentile among youth (Kazdin & Petti, 1982). Internal consistency for the CDI has been demonstrated to fall in the range of .70-.86 for the overall measure (Kovacs, 1985). For the purposes of this study, the total score was used.

#### *Hollingshead Socioeconomic Status*

The Hollingshead Two-Factor Scale, assessing parent occupation and education, was used to assess socioeconomic status (SES). SES scores range from 1-5 with 1 being in the highest SES bracket and 5 being in the lowest.

#### *Physical measures*

Children’s heights were measured three times to the nearest millimeter by a calibrated electronic stadiometer (Holtain, Crymych, Wales), and weights were measured to the nearest 0.1 kg by a calibrated digital scale (Scale-Tronix, Wheaton, IL). Body weight and the average of three heights were used to calculate BMI.

To assess pubertal development, among girls, breast development was assigned according to the stages of Tanner, (Marshall & Tanner, 1969), and for boys, testicular volumes were measured according to Prader (Tanner, 1981). Pubertal stage and testicular volume reflect neurocognitive and physical maturity (Marshall & Tanner, 1969, 1970).

### **Data Analysis**

#### *Data handling and missing data*

Data was examined using descriptive statistics and distributions for each variable of interest. Skewedness and kurtosis were examined, and skewed data was transformed and outliers recoded when necessary.

#### *Dependent variable*

BMI at all time points from the start of the study through the six month time point constituted the dependent variable for weight loss. Similarly, BMI at all time points ranging from six months through one year constituted the dependent variable for weight regain. Because height data was unavailable at every time point, BMI at each time point was calculated based on measured weight and predicted height values. To interpolate height data at timepoints when this data was unavailable, a separate linear regression model was generated for each adolescent, based on participants' age and existing height data. The slope of the estimated height curve over time was constrained to be greater than or equal to zero. This method accommodated missing data and corrected for measurement error. Relatively short ( $\leq 1$  year) follow-up intervals, in combination with relatively small changes in height, rendered that linear regression models, as opposed to nonlinear growth curves, constituted the best-fitting model. Per recommendation, BMI rather than BMI Z-scores were used to examine adolescent's BMI trajectories over time (Berkey & Colditz, 2007; Cole et al., 2005).

#### *Primary independent variable*

Our primary independent variables of interest were binge and LOC eating at baseline and post-treatment, and medication assignment (orlistat versus placebo). Participants were selected for the current analysis based on having an EDE assessment at baseline. Therefore, all baseline data were present. However, a number of participants did not complete a post-treatment EDE; for analysis of the impact of change in binge eating and post-treatment binge eating, only those

adolescents who completed both baseline and post-treatment assessments were included in this analysis. We considered using multiple imputation to predict EDE scores at the six-month time point however, the only factor associated with baseline binge eating was depression, and no factors that we know of adequately predicted whether an adolescent would continue to binge eat, start binge eating, or stop binge eating, during the course of treatment. Therefore, we concluded that we had insufficient data upon which to predict our imputation, and we elected to restrict analysis of post-treatment EDE data to those participants who were administered an EDE at post-treatment.

### *Covariates*

Between-subjects covariates included age, sex, race, SES, pubertal status, baseline BMI, and depressive symptoms. All participants completed all baseline demographic measures, and the missing data at baseline were four African American children's CDI measurement. Because of the paucity of missing baseline data, we used simple imputation based on race and sex to compute these four children's missing CDI scores. All other covariates were available for all participants.

### *Preliminary Analyses*

Descriptive statistics were used to examine the demographic and anthropometric characteristics of the entire sample, and prevalence of binge and LOC eating at baseline and post-treatment were calculated. Change in binge eating was examined in two ways: Matched-samples t-tests were used to examine the change in frequency of binge eating from baseline through post-treatment, and a McNemar's Chi Square was used to examine whether there were differences in prevalence of binge and LOC eating from baseline to post-treatment.

Independent samples t-tests were used to examine whether there were baseline demographic differences between individuals with and without binge/LOC episodes. Variables examined included age, sex, race, pubertal status, socioeconomic status, randomization to orlistat versus placebo, depression at baseline, and BMI at baseline. Logistic regressions were then used to examine potential differences between adolescents who dropped out of treatment and those who remained in the study. Variables examined included age, sex, race, pubertal status, SES, presence and frequency of binge/LOC eating, randomization to orlistat versus placebo, CDI at baseline, BMI at baseline, and BMI change within the first three months of study.

#### *Primary Data Analysis*

Linear mixed models were used to examine the impact of binge eating at baseline, binge/LOC eating at post-treatment, and change in binge/LOC eating, on BMI. Presence of binge/LOC eating and medication assignment constituted fixed between-subjects factors. For our primary analyses, binge/LOC eating were conceptualized categorically, due to the abnormal distribution of binge/LOC episodes: it was expected that the majority of adolescents would report no binge/LOC episodes. Further, it was expected that all participants who endorsed eating episodes would share some common characteristic related to their eating behavior, and thus would be better conceptualized as a coherent group. For baseline and post-treatment binge eating, all participants who endorsed one or more binge episodes were included in the binge group. For change in binge status, the difference between number of episodes endorsed at baseline and post-treatment was computed. Participants were then categorized into three groups: those who never engaged in binge episodes, those who stopped or decreased binge eating, and those who started, maintained, or increased binge eating. Binge and LOC eating were also analyzed as continuous variables.

Fixed, between-subjects covariates included in the models were age, sex, race, socioeconomic status, pubertal status, baseline BMI, and depressive symptoms (CDI). Age, sex, race, and pubertal status were included in analyses because of their known associations with weight status and weight loss over time. Socioeconomic status is also thought to be potentially influential in adolescents' weight and weight outcomes. Finally, baseline BMI and depressive symptoms are thought to influence weight outcomes; baseline BMI has been correlated with both greater weight loss and greater weight re-gain. Depressive symptoms are inversely correlated with weight loss. Time, time squared, time by race, time by CDI score, and time by baseline BMI constituted within-subjects covariates in the models. The model also included random, subject-specific intercepts.

#### *Correlation Structure*

Compound Symmetry (CS) is the default correlation structure used in mixed models. Compound symmetry assumes that all data points in a series (i.e. a single participant) correlate equally with all other data points. For example, in a data series consisting of three time points, time 1 would correlate equally with time 2 and time 3. By contrast, AR1 is a type of correlation structure that assumes that degree of correlation between time points varies according to the distance between time points. For example, time 1 would correlate more closely with time 2 than time 3. Another assumption made by AR1 is that all time points are equally spaced (i.e. time 1 and time 2 are separated by the same number of days as time 2 and time 3). In a weight loss study, it is possible that consecutive time points are correlated more strongly than non-consecutive time points; however, this is not always the case. Further, the design of the present study is such that at the beginning of the study, visits are separated by one week, while at the end of the study, visits are separated by approximately six months. This design would violate the



assumption of equidistant time points of AR1. Compound symmetry and AR1 were thus both examined to determine which model demonstrated the best fit to the data.

## RESULTS

### Preliminary Data Analysis

#### *Participant Characteristics*

One-hundred and sixty-eight adolescents were enrolled in the study at baseline. Adolescents in the study were substantially overweight (BMI mean  $\pm$  SD =  $41.53 \pm 9.19$ , range =  $27.05 - 87.39 \text{ kg/m}^2$ ), were mostly female (65%), African-American (61%), and their mean age was  $14.5 \pm 1.4\text{y}$  (range =  $12.0 - 17.5\text{y}$ ). Baseline participant characteristics are displayed in table 1. At baseline, 34 (20.2%) participants endorsed at least one binge episode, and 47 (28.1%) participants endorsed either type of LOC episode. Number and percentage of participants endorsing various types of eating episodes are shown in table 2. Participants with versus without binge eating did not differ in terms of baseline BMI, age, sex, race, socioeconomic status, pubertal status, or randomization to orlistat versus placebo (Table 3). However, adolescents with binge eating had significantly greater depressive symptoms compared to those without binge eating. Differences between adolescents with and without LOC eating were similar (Table 3b), however, adolescents with LOC eating were significantly older than those without LOC eating, a difference that was not present between binge and non-binge eaters.

#### *Prevalence of Binge/LOC eating*

The majority of adolescents ( $n = 29$ ) who endorsed binge eating did not meet full criteria for BED, and the median number of binge episodes during the month prior to assessment, among those who did endorse binge episodes, was 1 (Figure 2a). At post-treatment, 98 participants never experienced binge eating, 27 participants who endorsed binge eating at baseline either

stopped or decreased the frequency of binge eating, and 22 participants with and without baseline binge eating either started binge eating, or maintained or increased binge frequency.

Among participants who endorsed binge eating at baseline, frequency of binge episodes generally decreased from baseline through six months (mean number of episodes at baseline = 4.12; mean number of episodes at post-treatment = 0.98; paired  $t = 3.14$ ;  $p < .01$ ). A similar proportion of adolescents who endorsed no episodes at baseline initiated binge eating during the course of treatment. Therefore, there was no overall significant change in proportion of adolescents endorsing binge eating ( $p = .47$ , McNemar's Chi Square). Figures 4a-f display baseline prevalence of binge and LOC eating among adolescents with  $\geq 1$  episode, and changes in frequency of binge episodes, for adolescents who did (20.2%) and did not (79.8%) endorse binge/LOC eating at baseline.

#### *Attrition*

Of 168 participants, 22 dropped out of the study by the end of randomized treatment, constituting an 86.9% rate of treatment completion. By contrast, only 48.8% ( $n = 82$ ) of participants remained in the study throughout the entire open-label orlistat phase of treatment. Adolescents who completed the active treatment phase did not differ significantly from those who did not in terms of any covariate, randomization to orlistat versus placebo, or baseline BMI. The only variable that predicted likelihood of treatment non-completion at six months was success at the three month time point; less weight loss at three months was associated with treatment non-completion at six months ( $OR = 2.51$ ,  $p < .01$ ). Similarly, weight loss at three months ( $OR = 1.29$ ,  $p = .04$ ), but not six months ( $OR = 1.07$ ,  $p = .4$ ), predicted completion of the entire open-label treatment phase.

#### *Correlation Structure*

For mixed model analyses, two possible correlation structures: compound symmetry (CS), and AR1, were examined. Examination of goodness of fit indices (AIC and BIC) for CS and AR1 correlation structure types revealed no differences in goodness of fit across correlation structure type. Therefore, we chose to use CS both because it is the default and because AR1 does not account for unequal spacing of data points.

## Specific Aims

### *Aim 1: Impact of baseline binge/LOC eating on weight outcomes*

#### *A. Impact of baseline binge/LOC eating on weight loss*

Presence of binge eating at baseline had no overall main effect on weight loss from baseline through six months ( $p = .7$ ). However, there was a significant interaction between binge eating and medication assignment during the course of randomized treatment ( $F(1, 1908) = 9.6$ ,  $p < .01$ ). Among adolescents randomized to take orlistat, those who reported binge eating had significantly less BMI loss compared to adolescents who never reported binge eating ( $F(1, 1002) = 4.6$ ,  $p = .03$ ). For an average 6-month follow-up interval, an adolescent taking orlistat who did not report binge eating would be estimated to lose 0.5 BMI units more than an adolescent who endorsed binge eating. However, for adolescents taking placebo, binge eating was unassociated with weight loss ( $p = .09$ ). When LOC eating within the past month was used to predict weight loss, there was an overall main effect of LOC ( $F(1, 1900) = 5.5$ ,  $p = .02$ ), but no interaction with medication ( $p = .3$ ). The magnitude of impact was less than that of binge eating: over a 180-day interval, an adolescent with LOC would be expected to lose 0.2 BMI units less than an adolescent without LOC would be expected to lose.

#### *B. Impact of baseline binge/LOC on weight regain*

The presence of neither baseline binge nor LOC eating impacted weight regain from the six-month through the one-year time point (all  $p$ 's = ns).

### *Aim Two. Impact of post-treatment binge/LOC eating on weight outcomes*

#### *A. Impact of post-treatment binge/LOC eating on weight regain*

Binge eating at post-treatment had a significant main effect on weight outcome during the open-label phase of treatment ( $F(1, 349) = 4.8$ ,  $p = .03$ ), with adolescents who endorsed binge

eating at post-treatment regaining more weight than those who did not endorse binge eating. There was also a significant interaction between post-treatment binge eating and medication during the randomized phase of treatment; for adolescents who were assigned orlistat during the randomized phase of treatment, endorsing binge eating was associated with more weight regain compared to those without binge eating during the open-label phase ( $F(1, 165) = 6.2, p = .01$ ). For adolescents taking orlistat, those with binge eating at post-treatment followed for 180 days would be estimated to regain 1.1 BMI units more than an adolescent without post-treatment binge eating. This effect was not present for adolescents who took placebo during the randomized phase ( $p = .8$ ). Similarly, there was a significant overall main effect of LOC eating ( $F(1, 330) = 4.3, p = .04$ ). For all adolescents, endorsement of post-treatment LOC eating was associated with regaining 0.8 BMI units more than predicted during an estimated 180 day follow-up interval. However, there was no interaction between medication assignment and LOC eating.

### ***Aim Three. Impact of change in binge/LOC on weight outcomes***

#### ***A. Impact of change in binge/LOC on weight loss***

When we examined the impact of a change in binge eating, adolescents were categorized into three groups: (1) never binge ate, “never,” (2) stopped or decreased binge eating, “stop/decrease,” and (3) started, maintained, or increased binge eating, “start/increase.” During the randomized controlled trial, there was an overall main effect of binge group on weight loss: an adolescent in the “never” group followed for 6 months would be estimated to lose an additional 0.78 BMI units compared to an adolescent in the “start/increase” group ( $F(2, 1647) = 10.66, p < .01$ ). When adolescents randomized to orlistat and placebo were analyzed separately, among the placebo group only, both the “never” and the “stop/decrease” groups experienced

greater BMI loss compared to adolescents in the “start/increase” group (relative estimated BMI loss compared to ‘start, maintain or increase group,’ = 1.6 BMI units over a 6 month interval, for both groups). With regard to change in LOC frequency, there was a trend for adolescents who never experienced LOC to lose more weight during treatment ( $F(2, 1635) = 2.44, p = .08$ ), compared to the “start/increase” group.

*B. Impact of change in binge/LOC on weight regain*

During the open-label phase of treatment, there was a trend toward a main effect for the “never” binge group to regain less weight compared to those who started or increased binge eating (relative estimated regain in BMI for 180 day interval compared to “start/increase” group = 0.86,  $F(2, 350) = 2.86, p = .06$ ). Change in LOC frequency, however, did not significantly affect weight regain during the follow up phase ( $p = .3$ ).

***Post Hoc Analyses***

*Impact of ever experiencing binge eating*

In a post-hoc analysis, we grouped all adolescents who ever experienced binge eating at either baseline or post-treatment to those who never endorsed binge eating at either time point. There was a significant main effect such that adolescents who had ever endorsed binge eating lost less weight during treatment ( $F(1, 1649) = 7.95, p < .01$ ) and regained more weight after treatment ( $F(1, 353) = 5.23, p = .02$ ) compared to those who never endorsed binge eating. For LOC eating, ever reporting LOC was associated with less weight loss during treatment ( $F(1, 1637) = 4.6, p = .03$ ), but not more weight regain after treatment ( $p = .3$ ).

## **DISCUSSION**

### **Summary of Findings**

In this study, we examined the impact of binge and loss of control eating on weight trajectories of adolescents during and after participation in a double-blind, placebo-controlled weight-loss trial testing the effects of orlistat. We found that there was no overall main effect of baseline binge eating on weight loss, but that among adolescents taking orlistat during the randomized controlled portion of the trial, baseline binge eating was associated with less weight loss during randomized treatment. For LOC eating, there was an overall main effect for LOC to be associated with less weight loss during treatment. During the open-label phase of treatment, post-treatment, but not baseline, binge and LOC eating were associated with greater weight regain.

### **Implications**

Consistent with Braet and colleagues (Braet et al., 2004), we found no overall detrimental impact of baseline binge eating on weight loss. This is, however, inconsistent with some adult studies, which found that binge eating appears to hinder weight loss efforts, producing less weight loss, greater weight regain, and increased risk of dropping out of treatment (Blaine & Rodman, 2007; Sherwood et al., 1999; Yanovski, Nelson, Dubbert, & Spitzer, 1993). An important distinction between our sample and adult samples is that the latter studies examined the impact of full-syndrome BED, and not sub-threshold binge eating, on weight loss. It is likely that frequent and severe binge episodes, characteristic of BED among adults, would be more likely to have a robust, overall influence on weight outcome compared to sporadic episodes characteristic of most participants in the present study. In our sample, only five adolescents met



full criteria for BED. Further, within our cohort, all adolescents entered the study equally overweight regardless of binge eating. In the absence of an active intervention, adolescents with and without binge eating would likely continue to have equal risk of continued weight gain, whether this be due to binge eating, environmental factors, or other factors, emphasizing etiological differences in development of obesity.

Despite no overall main effect of binge eating on weight loss, we did find that among participants taking orlistat, adolescents without binge eating lost more weight during treatment. Several potential mechanisms may explain why binge eating appears to hinder weight loss for adolescents taking orlistat, but not for those taking placebo. First, despite being a blinded trial, the side effects of orlistat rendered that most adolescents were aware of whether they had been randomized to orlistat versus placebo. It is possible that binge eaters on orlistat presumed it to be a “magic pill” and became disinhibited in terms of their eating, resulting in excess intake. Secondly, individuals reporting binge eating might have avoided medication to prevent side effects when they knew they would be engaging in binge episodes. Finally, it is possible that the mechanism of orlistat is more compatible with environmentally-induced (e.g., insufficient exercise, consuming high-fat foods), compared to “binge-eating-induced” obesity. Adolescents without binge eating may simply consistently overeat by a very small amount, a pattern of caloric excess that could be directly countered by orlistat. By contrast, adolescents with binge eating may be more likely to occasionally overeat by a vast amount, a pattern of caloric excess less adequately eliminated by orlistat.

When we examined change in binge eating, we found that adolescents who never experienced binge eating lost more weight and regained less weight, compared to those who started or increased binge eating. Among the placebo group, those who stopped or decreased

binge eating also lost significantly more weight than those who started or increased binge eating. These findings converge with Gorin and colleagues' findings (2008), in which individuals who stopped binge eating or never binge ate lost more weight compared to those who continued to binge eat.

It is likely that the high percentage of participants who stopped or decreased binge eating explains why baseline binge eating failed to hinder weight loss. When we examined post-treatment binge/LOC eating and change in binge and LOC eating as predictors of weight outcomes, our findings support that in fact, whether a participant experiences pathological eating at post-treatment, and how their behavior changed over the course of weight loss treatment, had greater implications for weight outcomes than baseline binge eating alone. New findings from the Look AHEAD trial among adults support this hypothesis (Gorin et al., 2008). Gorin and colleagues found that, over a one year time period, adults who endorsed binge eating at pre but not post treatment, and those who endorsed binge eating at neither time point, lost more weight compared to those who either initiated binge eating during treatment or those who endorsed binge eating at both time points. It appears that the experience of binge eating at post-treatment has greater influence on weight regain compared to presence of binge eating at baseline. However, baseline binge eating may predict increased likelihood of binge eating at post-treatment. The predictive value of binge/LOC eating for subsequent weight change may be dampened by the malleability of binge eating during weight loss treatment (Braet et al., 2004; Gorin et al., 2008). The majority of participants with binge eating stopped binge eating, and many adolescents started binge eating, during treatment.

Several of our findings support that behavior change, seemingly catalyzed by active weight loss treatment, may not be long-lasting. First, decreased frequency of LOC episodes

from baseline to post-treatment is associated with greater weight regain. Also, according to our data, reportedly stopping or decreasing binge frequency does not seem to consistently predict less weight regain during the open-label phase. Ours and others' (Braet et al., 2004; Gorin et al., 2008) findings raise the question of whether stopping or decreasing binge/LOC eating is maintained after treatment, and for how long. It is possible that pathological eating may be temporarily suppressed during weight loss treatment, but may re-emerge after the conclusion of active intervention. Understanding the sustainability of behavior change induced by active weight loss treatment has important implications for how treatment of both obesity and pathological eating is approached. Indeed, a more suitable treatment for individuals who report binge and LOC eating might involve a greater focusing on reducing such behaviors. A number of psychological treatments designed to decrease BED have demonstrated effectiveness and are associated with modest weight loss or weight maintenance (Tanofsky-Kraff et al., 2007).

### **Limitations**

A significant limitation in our study is the inability to account for medication compliance during the open-label phase of treatment. BMI change is likely affected by adherence to the voluntary open-label orlistat regimen, however, we are unable to account for this during open-label treatment. We do know that nearly all participants who remained under study during this phase of treatment received medication at bi-monthly appointments. However, whether participants actually complied with taking the medication is less clear. A second limitation is that the open-label orlistat phase of the study was characterized by substantial (~50%) attrition. However, mixed models accommodate variable follow-up intervals, and so treatment drop-outs were included in analyses. Other limitations to our study included the relatively small sample size and the unexpected nature of our findings—given that the interactions between binge eating

by medication group were not expected, our findings should be considered hypothesis generating as opposed to hypothesis driven, and therefore requiring replication. Strengths of our study include an ethnically diverse sample, the use of a structured interview to assess binge eating, and the inclusion of multiple time points per participant.

### **Future Directions**

Our findings emphasize etiological differences in the development of obesity among youth. The differential impact of binge eating on treatment success among adolescents taking orlistat versus placebo suggests that potentially different mechanisms drive the accumulation of excess weight for those with and without binge eating. Binge eating during adolescence may be sporadic and subtle, and not yet engrained into one's behavioral repertoire. However, presence of sub-threshold binge eating may constitute a marker for future development of full-syndrome BED. It is also apparent that such behavior is malleable during and after weight loss treatment. Despite that such behavior may often cease during active weight loss treatment, an important research direction is to investigate the sustainability of such behavior change, among youth and others. Adolescence is a key time wherein addressing binge eating behaviors among those seeking weight loss treatment may be warranted, particularly given that disordered eating patterns frequently emerge during this developmental stage (Mussell et al., 1995; Reas & Grilo, 2007).

Table 1.

**Participant characteristics (N = 168)**

<u>Characteristic</u>	<u>N</u>	<u>Percent</u>
<u>Gender</u>		
Male	58	34.5
Female	110	65.5
<u>Race/Ethnicity</u>		
African American	103	61.3
Caucasian	65	38.7
<u>Randomization</u>		
Orlistat	86	51.2
Placebo	82	48.8
<u>Characteristic</u>	<u>Mean/median</u>	<u>Standard Deviation/Range</u>
Age	14.51	1.39
Baseline BMI	41.53	9.19
Child Depression Index	6.74	5.59
*(n=164)		
<u>Characteristic</u>	<u>Median</u>	<u>Range</u>
Pubertal Status	4	1-5
Socioeconomic Status	3	1-5

*Note.* BMI = body mass index.

\*Simple imputation based on sex and race used for 4 missing values

Table 2.

**Number and types of eating episodes**


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<u>Type of Episode</u>	<u>N</u>	<u>Percent</u>
<u>Objective Binge Episodes</u>		
Yes	34	20.2
No	134	79.8
<u>Subjective Binge Episodes (n=167)</u>		
Yes	21	12.6
No	146	87.4
<u>Loss of control Episodes (n=167)</u>		
Yes	47	28.1
No	120	71.3

Table 3.

**Participant characteristics of adolescents with and without binge and loss of control eating**

(a) Baseline characteristics of binge versus non-binge and eaters

<u>Characteristic</u>	<u>Binge</u>	<u>No Binge</u>	<u>p-value</u>
<u>n</u>	34(20.2%)	134(79.8%)	--
<u>BMI (kg/m2)</u>	41.9±9.7	41.4±9.1	ns
<u>Age(y)</u>	14.8±1.6	14.4±1.3	ns
<u>Sex</u>			
Male	44%	32%	ns
Female	56%	68%	
<u>Race</u>			
African American	53%	63%	ns
Caucasian	47%	37%	
<u>Randomization</u>			
Orlistat	53%	51%	ns
Placebo	47%	49%	
<u>SES(1-5)</u>	3 (median)	3 (median)	ns
<u>Puberty(1-5)</u>	4 (median)	5 (median)	ns
<u>Depressive Symptoms</u>	9.4±6.3	6.0±5.1	p=.001

## (b) Baseline characteristics of LOC versus non-LOC eaters

<u>Characteristic</u>	<u>LOC</u>	<u>No LOC</u>	<u>p-value</u>
<u>n</u>	47(28.1%)	120(71.9%)	--
<u>BMI (kg/m2)</u>	42.9±11.0	40.9±8.4	ns
<u>Age(y)</u>	14.8±1.6	14.4±1.3	ns
<u>Sex</u>			
Male	40%	32%	ns
Female	60%	68%	
<u>Race</u>			
African American	62%	61%	ns
Caucasian	38%	39%	
<u>Randomization</u>			
Orlistat	51%	51%	ns
Placebo	49%	49%	
<u>SES(1-5)</u>	3 (median)	3 (median)	ns
<u>Puberty(1-5)</u>	4 (median)	5 (median)	ns
<u>Depressive Symptoms</u>	9.6±6.3	5.6±4.8	p<.001



Table 4.

**Summary of findings**

<i>Hypothesis</i>	<i>Supported?</i>
<b><i>Aim 1A.</i></b>	
a. Adolescents with $\geq 1$ episode of binge eating at baseline will lose less weight during treatment	No main effect; however, was supported among adolescents taking orlistat
b. Adolescents with $\geq 1$ episode of LOC eating at baseline will lose less weight during treatment	Yes
<b><i>Aim 1B</i></b>	
a. Adolescents with $\geq 1$ episode of binge eating at baseline will regain more weight during the open-label phase	No
b. Adolescents with $\geq 1$ episode of LOC eating at baseline will regain more weight during the open-label phase	No
<b><i>Aim 2</i></b>	
a. Adolescents with $\geq 1$ episode of binge eating at post-Treatment will regain more weight during the open-label phase	Yes; also found an interaction with medication.  When analyzed separately, this effect was present for adolescents taking orlistat but not placebo

b. Adolescents reporting  $\geq 1$  episode of LOC eating at post-treatment will regain more weight during the open-label phase

Yes

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### ***Aim 3A***

a. Adolescents who stop or decrease binge eating will lose more weight compared to other adolescents	No; Adolescents who <i>never</i> binge eat lost more weight than adolescents who started or increased binge eating; also found an interaction with medication. When analyzed separately, adolescents in the placebo group who stopped or decreased binge eating also lost more weight than those who started/increased
b. Adolescents who stop or decrease LOC eating will lose more weight compared to other adolescents	No; rather, there was a trend for adolescents who <i>never</i> experience LOC eating to lose more weight compared to those who start/increase

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### ***Aim 3B***

a. Adolescents who stop or decrease binge eating will regain less weight compared to other adolescents	No; there was a trend for adolescents who <i>never</i> experience binge eating to regain less weight compared to those who start/increase
b. Adolescents who stop or decrease LOC eating will regain less weight compared to other adolescents	No

Figure 1.

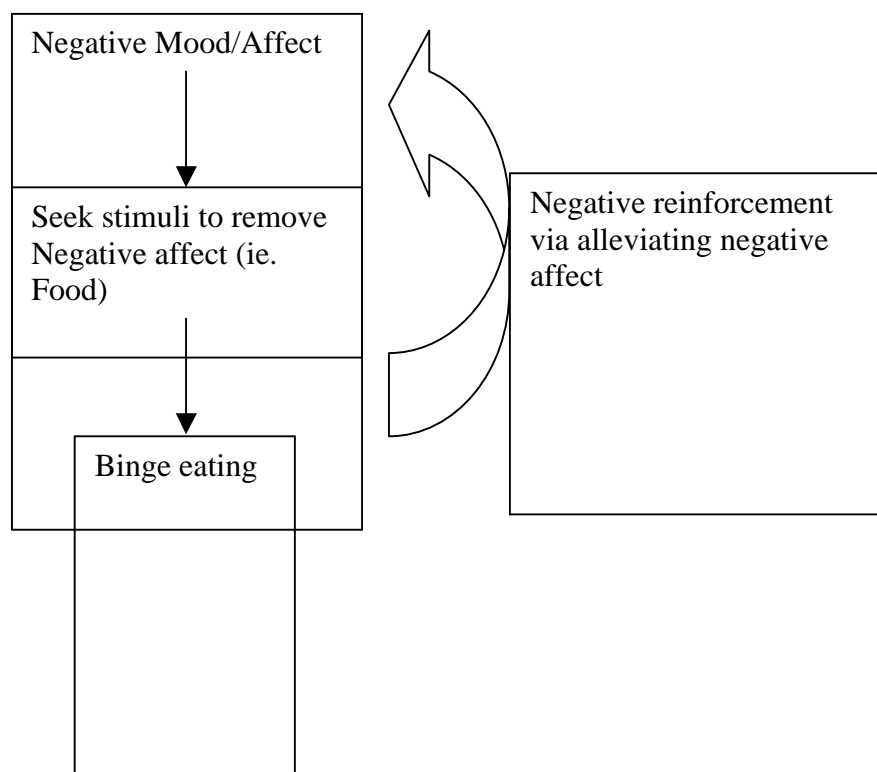
**Affect Regulation Theory**

Figure 2.

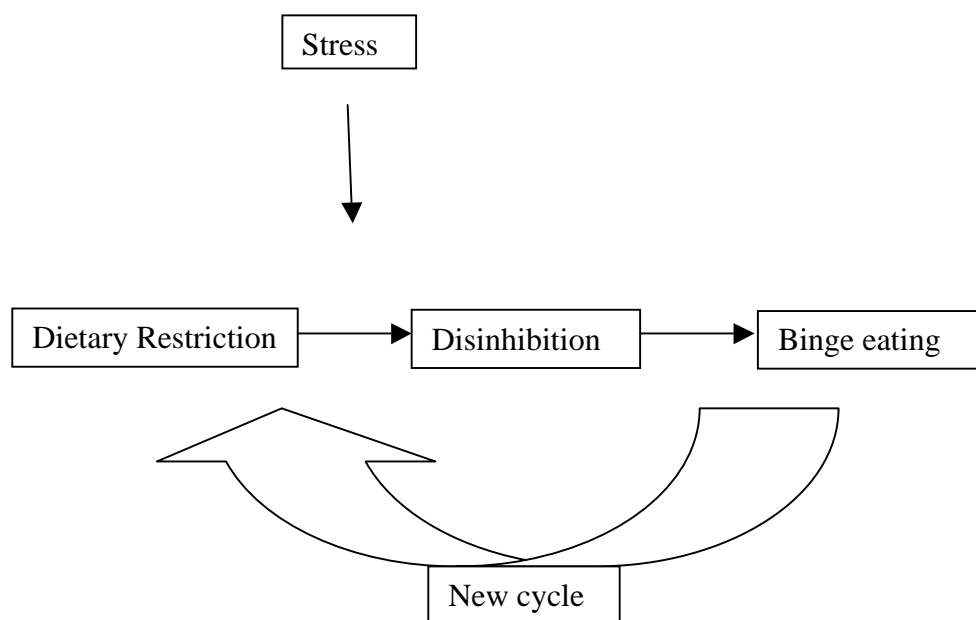
**Restraint Theory**

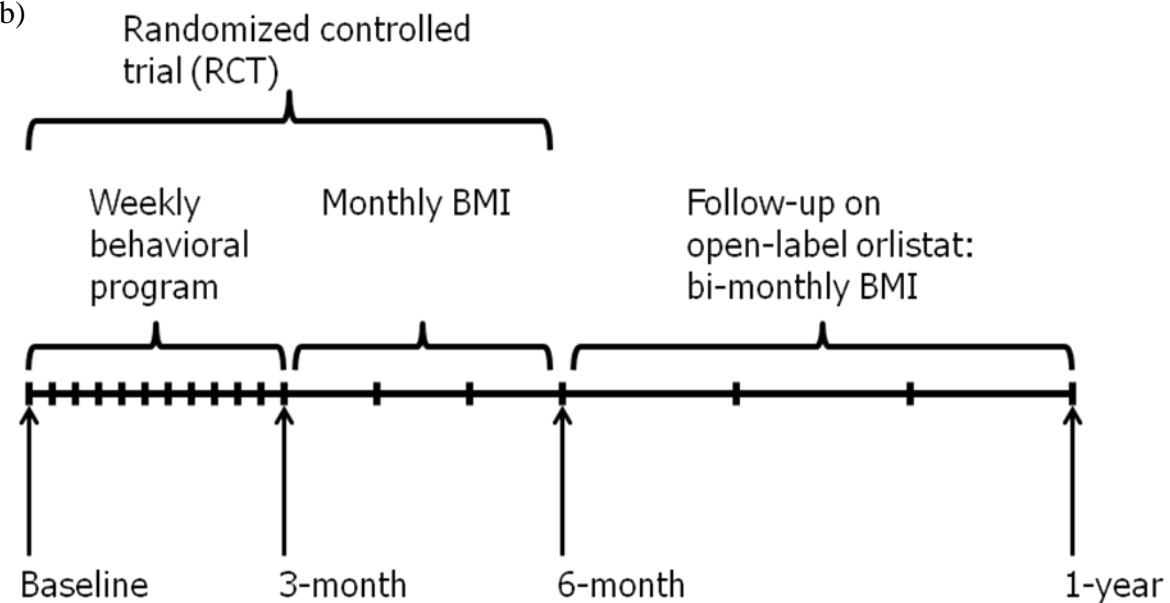
Figure 3.

**Study Timeline**

(a)

	Baseline	Months 1-3	Months 4-6	Post-treatment	Months 6-12	Follow-up (year 1, 1.5, 2, 2.5, 3)
BMI measured	X	X	X	X	X	X
Eating pathology measured	X			X		
Psychological symptoms measured	X			X		
Behavior Modification		X				
Orlistat or placebo		X	X			
Open-label Orlistat					X	

(b)



☐ Binge eating  
☐ Depressive Sx  
☐ Anxiety Sx

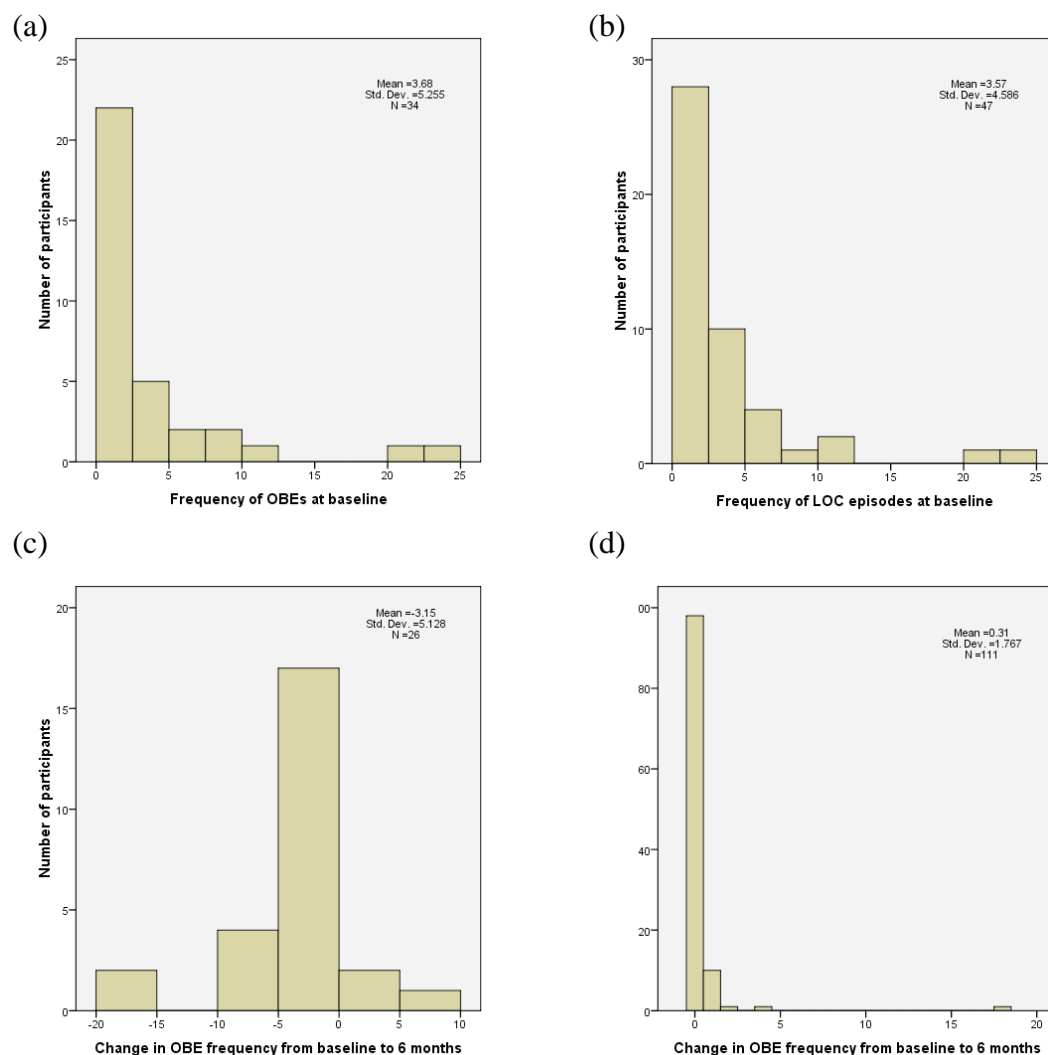
☐ Binge eating  
☐ Depressive Sx  
☐ Anxiety Sx

**| = BMI measured**

Figure 4.

### Prevalence of binge and loss of control eating, change scores for binge and loss of control eating

(a) Frequency of OBEs for participants endorsing  $\geq 1$  OBE at baseline, (b) Frequency of LOC episodes for participants endorsing  $\geq 1$  LOC episode at baseline, (c) Change in frequency of OBEs for participants endorsing  $\geq 1$  OBE at baseline, (d) Change in frequency of OBEs for participants endorsing NE at baseline, (e) Change in frequency of LOC episodes for participants endorsing  $\geq 1$  LOC episode at baseline, (f) Change in frequency of LOC episodes for participants endorsing NE at baseline



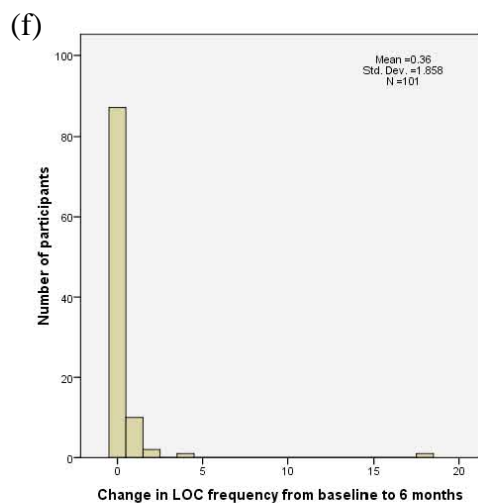
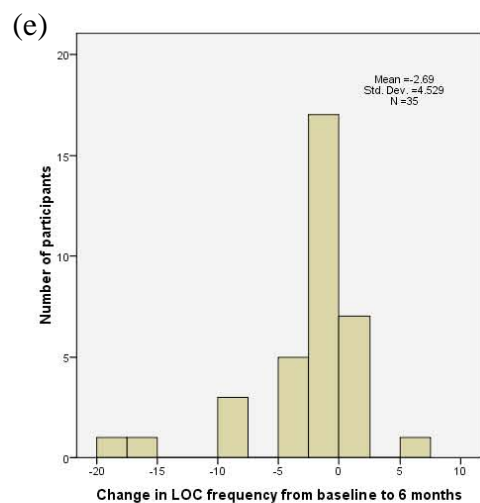


Figure 5.

**Predicted body mass index (BMI, kg/m<sup>2</sup>) change during randomized treatment phase based on binge eating and medication assignment**

(a) Weight loss among adolescents taking placebo with and without binge eating, (b) Weight loss among adolescents taking orlistat with and without binge eating

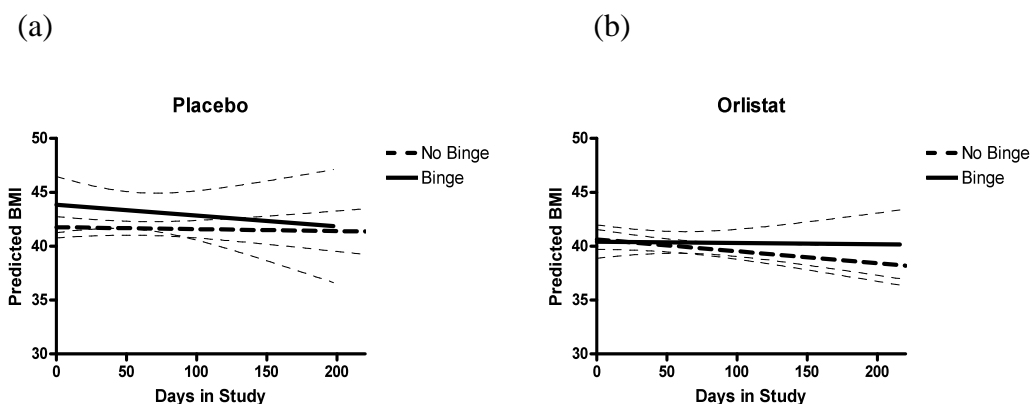




Figure 6.

**Predicted BMI change during open label phase based on binge and loss of control eating and medication assignment**

(a) Weight regain among all adolescents with and without binge eating, (b) Weight regain among adolescents taking placebo with and without binge eating, (c) Weight regain among adolescents taking orlistat with and without binge eating, (d) Weight regain among all adolescents with and without LOC eating

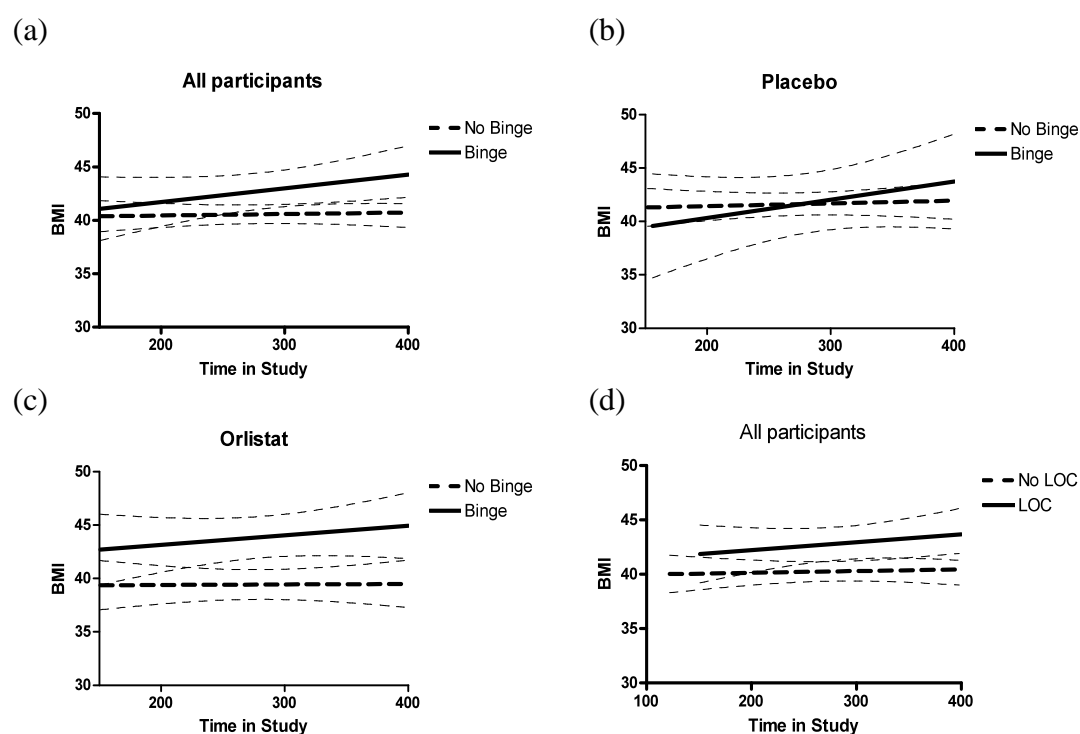
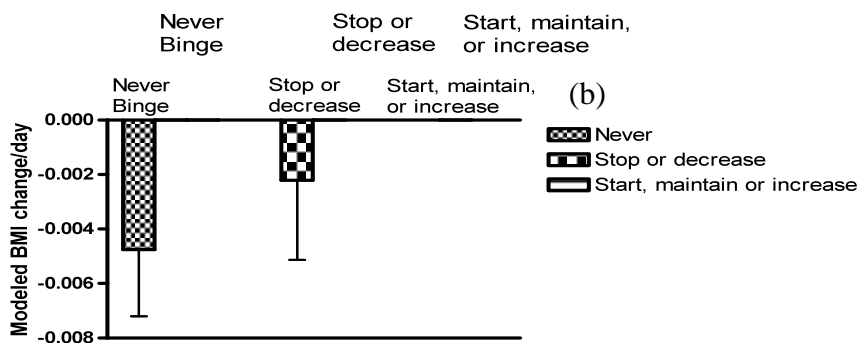
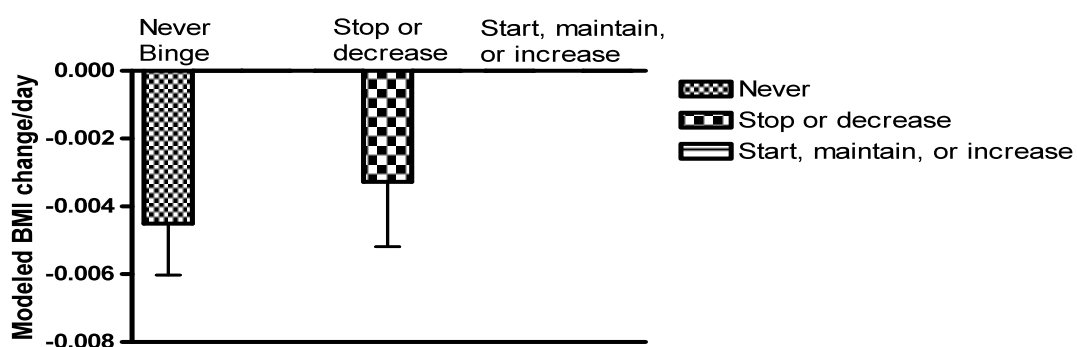


Figure 7.

**Predicted BMI change during randomized treatment phase based on change in binge eating**

(a) Weight loss by binge group: (1) Never, (2) Stop or decrease, and (3) Start, maintain, or increase, during the randomized phase of treatment, (b) Weight regain by binge group during the open-label phase of treatment

(a)



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